REMARKS

In the outstanding Office Action, claims 1-4, 11-19 and 23-24 were presented for examination. Claims 1-4, 11-19 and 23-24 were rejected on formal grounds under 35 U.S.C. §112 and for failure of the specification to comply with the written description requirement. In addition, rejection was advanced on the basis of 35 U.S.C. §102 against claims 1-2, as being anticipated by references to Montal et al. and Fasshauer et al.

The Office Action has been most carefully studied. Applicant appreciates the withdrawal of objections and rejections, as noted in the Office action. In this amendment applicant has amended claims 1-2, 13, 15 and 16 and has explained how the claims now meet the statutory requirements for patentability. Accordingly, as will be discussed in detail below, it is believed that the application is clearly in condition for allowance.

Applicant Name

The Office is respectfully requested to change its records to correct the name of the first inventor to read as it is shown in the declaration, namely

"Ma Clara Blanes Mira".

(There is no "i" in "Blanes".)

Power of Attorney and Correspondence Address Indication

Applicant respectfully requests that the practitioners and correspondence address listed under customer number 00545 be entered pursuant to the power contained in the declaration filed 27 September 2004, and in the accompanying power from the assignee, be promptly entered to avoid possible delays in correspondence being received by the undersigned.

Claim Rejections - 35 U.S.C. §112 First Paragraph

Applicant respectfully traverses the rejection of claims 1-4, 11-19 and 23-24 for alleged failure to comply with the written description requirement of 35 U.S.C. §112 first paragraph on the ground that the specification as filed clearly shows that applicant was in possession of the presently claimed invention at the relevant date.

Of claims 1-4, 11-19 and 23-24, claims 1, 11, 13, 15 and 24 are independent claims, the remaining claims being dependent from the respective immediately preceding independent claim. Each of independent claims 1, 11, 13, 15 and 24 requires the presence, or the use, of a peptide whose complete amino acid sequence is selected from the amino acid sequence of SEQ ID NO:2 or the amino acid sequence of SEQ ID NO: 3.

Office practice regarding the written description requirement can be found in the MPEP (8th ed. Rev. 2), a relevant portion of which is set forth below:

2163.02 Standard for Determining Compliance With the Written Description Requirement

The courts have described the essential question to be addressed in a description requirement issue in a variety of ways. An objective standard for determining compliance with the written description requirement is, "does the description clearly allow persons of ordinary skill in the art to recognize that he or she invented what is claimed." *In re Gosteli*, 872 F.2d 1008, 1012, 10 USPQ2d 1614, 1618 (Fed. Cir. 1989). Under *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991), to satisfy the written description requirement, an applicant must convey with reasonable clarity to those skilled in the art that, as of the filing date sought, he or she was in possession of the invention, and that the invention, in that context, is whatever is now claimed. The test for sufficiency of support in a parent application is whether the disclosure of the application relied upon "reasonably conveys to the artisan that the inventor had possession at that time of the later claimed subject matter." *Ralston Purina Co. v. Far-Mar-Co., Inc.*, 772 F.2d 1570, 1575, 227 USPQ 177, 179 (Fed. Cir. 1985) (quoting *In re Kaslow*, 707 F.2d 1366, 1375, 217 USPQ 1089, 1096 (Fed. Cir. 1983)).

Whenever the issue arises, the fundamental factual inquiry is whether the specification conveys with reasonable clarity to those skilled in the art that, as of the filing date sought, applicant was in possession of the invention as now claimed. See, e.g., *Vas-Cath, Inc. v. Mahurkar*, 935 F.2d 1555, 1563-64, 19 USPQ2d 1111, 1117 (Fed. Cir. 1991). An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations using such descriptive means as words, structures, figures, diagrams, and formulas that fully set forth the claimed invention. *Lockwood v. American Airlines, Inc.*, 107 F.3d 1565, 1572, 41 USPQ2d 1961, 1966 (Fed. Cir. 1997). Possession may be shown in a variety of ways including description of an actual reduction to practice, or by showing that the invention was "ready for patenting" such as by the disclosure of drawings or structural chemical formulas that show that the invention was complete, or by describing distinguishing identifying characteristics sufficient to show that the applicant was in possession of the claimed invention. See, e.g., *Pfaff v. Wells Elecs., Inc.*, 525 U.S. 55, 68, 119 S.Ct. 304, 312, 48 USPQ2d 1641, 1647 (1998); *Regents of the University of California v. Eli Lilly*, 119 F.3d 1559, 1568, 43 USPQ2d 1398, 1406 (Fed. Cir. 1997); *Amgen, Inc. v. Chugai Pharmaceutical*, 927 F.2d 1200, 1206, 18 USPQ2d 1016, 1021 (Fed. Cir. 1991) (one must define a compound by "whatever characteristics sufficiently distinguish it"). (*Underlining added.*)

It may be seen that the extensive number of cases cited here include some of those cited in the outstanding Office action.

The Office practice with regard to written description requires that "An applicant shows possession of the claimed invention by describing the claimed invention with all of its limitations..." A written description of the subject matter claimed in claim 1 may be found throughout applicant's specification including, for example, at page 3 lines 11-20; page 4, line 14 to page 5 line 2; page 5 lines 3-4. These passages, and others in the specification, are believed to fully set forth the claimed invention with all of its limitations and to clearly show that applicant was in possession of the claimed invention. For example, page 3, lines 9-10 disclose that

> "Therefore, there is a need to find molecules of a smaller size that can be applied in cosmetics and medicine.".

The next paragraph, page 3, lines 11-20 presents the invention in broad terms as

> "including the discovery of smaller amino acid sequences, between 3 and 30 amino acids, deriving from the amino end (N-terminal domain) of protein SNAP-25."

Thus is an aspect of the invention clearly stated in broad terms. Some possible detailed structural and other characteristics that the new smaller peptides may have are set forth in the paragraphs at page 4, line 14 to page 5 line 2 where the particular peptides subject of the invention are defined by reference to SEQ ID NO: 1, by number of amino acids, by reference to homology and functionality, by their optical configuration, by their terminations and other characteristics that clearly convey to one skilled in the art that applicant was in possession of the claimed invention. Confirming such possession of the invention, the specification further discloses at page 5, lines 3-4 that:

> "Particular examples of peptides of the invention are those peptides that have sequences of amino acids shown in SEQ. ID NO. 2 and SEQ. ID NO. 3.".

Still further evidence of applicant's possession of the claimed invention is found at page 7, line 23 to page 8, line 9; and page 13, lines 14-32 where the results of tests

performed and studies made and the conclusions that may be drawn are described in detail.

Furthermore, "Possession of the invention may be shown in a variety of ways including description of an actual reduction to practice...". SEQ. ID NO. 2 and SEQ. ID NO. 3 appear in the sequence listing section of applicant's specification which sequence listing provides a structural description of the compounds. As described in Example 1, pages 12-14 of the specification, these and other compounds were synthesized, purified and analyzed and various biological properties were determined. This disclosure provides a clear and convincing description of not just "an actual reduction to practice" but of multiple reductions to practice. There is no requirement in patent law to show a reduction to practice of every embodiment of a claimed invention. Accordingly, the specification is believed clearly to meet the written description requirement for claim 1.

Synthetic peptides whose complete amino acid sequence is selected from the amino acid sequence of SEQ. ID NO. 2 or of SEQ. ID NO. 3, not only comprise the essence of claim 1 but they also comprise significant features of all other claims. Such other claims, 2-4, 11-19 and 23-24 also recite additional subject matter which is believed fully supported by a written description. In light of the described written description and reduction to practice of the compounds of SEQ. ID NO. 2 and SEQ. ID NO. 3 as well as other compounds, and in light of the description of the additional claim subject matter which appears throughout the specification, it is respectfully submitted that the specification clearly conveys to those skilled in the art that as of their filing date, applicant was in possession of the invention as claimed not only in claim 1 but also in each of claims 1-4, 11-19 and 23-24. Thus, all presently pending claims are believed to be in full compliance with the written description requirement.

Applicant has carefully studied the rationale for this rejection as set forth in section 7 on pages 3-6 of the Office action yet still has difficulty in understanding how

the rejection is being applied. Should the Office feel further action on this ground is warranted, which applicant believes is unquestionably not the case, the Office is respectfully requested to reformulate the rejection, if any, in customary manner to clarify what rationale is being applied to which claim.

Given that, in the outstanding Action, all the presently pending claims are grouped together and various of their features are then set forth in long lists, e.g. in the sentence that begins at line 5 from the bottom of page 3, and continues to line 7 of page 4, it is quite unclear as to what objection such as the supposed lack of disclosure of "a genus of variants" is being applied to any particular claim. Is this objection applied to SEQ. ID NO. 2 and SEQ. ID NO. 3, or to some other member or members of the list of claim elements that follows mention of a "genus of variants"? What specific rationale for rejection applies e.g. to claim 1? These problems continue in the long paragraphs beginning on pages 4 and 5 of the specification. To which claim does the criticism in the middle of page 5 that the skilled artisan cannot envision "all the contemplated peptides or peptide mixtures..."? To claim 1? Furthermore, where in patent law is there a requirement for the skilled artisan to be able to envision all the contemplated embodiments? To which claim does the finding on page 6 lines 3-4 apply that only some embodiments meet the written description requirement? To claim 1?

Clarification or withdrawal of the rejection based on the written description is respectfully requested. As explained hereinabove, applicant believes the original specification fully met the written description requirement for all presently pending claims. Accordingly, all statements to the contrary in the outstanding action are respectfully traversed for the reasons set forth hereinabove.

Claim Rejections - 35 U.S.C. §112 Second Paragraph

Claim 2 has been amended, without narrowing, to independently recite the subject matter considered to lack antecedent basis in claim 1. Claim 13 has been

amended to overcome the rejection of claims 13 and 14 to specify that the amount employed is an amount effective for the treatment of wrinkles or facial asymmetry. Similarly Claim 16 has been amended to overcome the rejection of claims 16-19 and 23 to specify that the amount employed is an amount effective for the treatment of a neurological disorder or a neurodegenerative disease.

Also, claim 15 has been amended in the manner kindly suggested by the Examiner to overcome the rejection. Claim 24 has been similarly amended.

Claim Rejections - 35 U.S.C. §102(b) Anticipation

Reference is now made to the rejection of claims 1 and 2 as anticipated by Montal et al., (WO97/34620). Claims 1 and 2 are believed clearly distinguished from Montal et al. as may be understood when full weight is given to the claim language. This calls for a synthetic peptide whose complete amino acid sequence is selected from the amino acid sequence of SEQ ID NO:2 or the amino acid sequence of SEQ ID NO: 3. Montal et al. discloses peptides obtained from the C-terminal domain of SNAP-25 and none of Montal's disclosed peptides has a sequence contained in SEQ ID NO:2 or SEQ ID NO: 3. Therefore, the sequences claimed in claim 1 and 2 could not be anticipated by this reference.

Nor is Montal et al. at all relevant to the patentability of any of applicant's claims Montal et al. does not remotely suggest that short peptides (less than 20 amino acids) outside the substrate binding domain of SNAP-25 and which are not close to, nor contain the regions cleaved by *Clostridium* neurotoxins, could act as inhibitors of neuronal exocytosis. On the contrary, the only short peptide outside the binding domain described in Montal's reference is Montal's SEQ ID NO:11 (49-MLDEQGQLER-59), which does not affect Ca^{2+}-dependent exocytosis (see page 23, lines 18-20). A person skilled in the art, reading Montal et al. accordingly encounters a technical

prejudice against using short sequences and against exploring sequences outside the substrate binding domain.

Fasshauer et al. discloses the full sequence of SNAP-25 and the peptides derived from the proteolysis of the ternary complex. Such peptides have a minimum length of 81 amino acids (fragments 2-83, 120-206 and 125-206, depending on the nature of the protease used) and accordingly do not meet the criteria of either claim 1 or claim 2. In addition, the reference suggests the importance of the C-terminal end of SNAP-25 (pp10357, last paragraph before the "Complexes formed between individual components of the minimal core complex" section), pointing a person skilled in the art away from testing any peptide from the N-terminal end of SNAP-25 and specifically any small peptide from such domain.

Furthermore, applicant's peptides are defined as being "synthetic" which term further distinguishes applicant's claims from Fasshauer et al. Applicant does not employ process language that is to be ignored pursuant to MPEP 2113. Rather applicant has employed a verb-derived qualifier which is well understood in the art and is commonly or even customarily used in this context to distinguish materials made by human agency from those of natural origin. See, e.g., *In re Garnero*, 412 F.2d 276, 279, 162 USPQ 221, 223 (CCPA 1979) (holding "interbonded by interfusion" to limit structure of the claimed composite and noting that terms such as "welded," "intermixed," "ground in place," "press fitted," and "etched" are capable of construction as structural limitations.) This case is cited in the MPEP at 2113.

In view of the above amendments and the discussion relating thereto, it is respectfully submitted that the instant application, as amended, is in condition for allowance. Such action is most earnestly solicited. If for any reason the Examiner feels that consultation with Applicant's representative would be helpful in the advancement of the prosecution, they are invited to call the telephone number below for an interview.

Respectfully submitted,

By: _____

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I hereby certify that this correspondence is being deposited with the United States Postal Service as first class mail in an envelope, postage prepaid, addressed to the Commissioner for Patents, P.O. Box 1450, Alexandria, VA 22313-1450 on July 6, 2005.

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